IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	:	
	:	Group Art Unit: 2151
Vladislav Olchanski *et al.*	:	
	:	Examiner: Karen C. Tang
Appln. No.: 09/996,475	:	
	:	Confirmation No.: 2706
Filed: November 20, 2001	:	
	:	Customer No.: 21967
For: PERFORMANCE OUTCOMES BENCHMARKING	:	

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

In response to the Office Action dated November 12, 2008, finally rejecting pending claims 1-21 and 23-30, Appellants respectfully request that the Board of Patent Appeals and Interferences reconsider and withdraw the rejections of record, and allow the pending claims, which are attached hereto.

REAL PARTY IN INTEREST

The Appellants, Vladislav Olchanski *et al.*, are the Applicants in the above-identified patent application. The Appellants have assigned their entire interest in the above-identified patent application to Chironet, LLC, 1899-E Billingsgate Circle, Richmond, Virginia 23233.

RELATED APPEALS AND INTERFERENCES

The Appellants, the Appellants' legal representative, and the Assignee are not aware of any other appeals or interferences which will directly affect, be directly affected by, or have a bearing on the Board's decision in this Appeal.

STATUS OF CLAIMS

Claims 1-21 and 23-30 are pending in the above-identified patent application. Claims 1-21 and 23-30 were finally rejected in the Office Action dated November 12, 2008. The final rejection of claims 1-21 and 23-30 is hereby appealed.

Claim 22 stands cancelled without prejudice.

Claims 1-21 and 23-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts ("Gatts") in view of U.S. Patent No. 6,650,932 to Menzie

et al. ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin").

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection of claims 1-21 and 23-30 in the Office Action dated November 12, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention, as set forth in claim 1, and as described and shown in the Specification and Figures 1 and 2 of the above-identified patent application, respectively, is directed to a method for collecting and reporting outcomes data for benchmarking medical procedures (*See*, e.g., page 11, lines 9-18). The method comprises collecting first outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities (*See*, e.g., step 200 in Figure 2, page 18, lines 8-14). The method also comprises establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more

medical procedures for the plurality of individuals (*See*, e.g., step 500 in Figure 2, page 31, line 18 to page 32, line 5). The method further comprises collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities (*See*, e.g., step 200 in Figure 2, page 20, lines 5-22). The method still further comprises converting at least some of the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result (*See*, e.g., page 31, line 21 to page 32, line 5). The method still further comprises comparing a selected one of the at least one outcomes result to the norm (*See*, e.g., page 33, lines 1-10, and page 35, lines 22-23). The method additionally comprises generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (*See*, e.g., step 600 in Figure 2, page 32, lines 21-24).

The claimed invention, as set forth in claim 11, and as described and shown in the Specification and Figures 1 and 2 of the above-identified patent application, respectively, is directed to a method for collecting and reporting outcomes data

for benchmarking surgical procedures (*See*, e.g., page 11, lines 9-18). The method comprises collecting first primary source surgical procedures outcomes data sets including a plurality of responses to a set of indicators associated with one or more surgical procedures for a plurality of patients in a first period of time via one or more user interfaces located at one or more surgical centers (*See*, e.g., step 200 in Figure 2, page 18, lines 8-14). The method also comprises establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with one or more surgical procedures for the plurality of patients (*See*, e.g., step 500 in Figure 2, page 31, line 18 to page 32, line 5). The method further comprises collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients in a second period of time via the one or more user interfaces located at the one or more surgical centers (*See*, e.g., step 200 in Figure 2, page 20, lines 5-22). The method still further comprises converting at least some of the second primary source surgical procedures outcomes data sets including

the plurality of responses to the set of indicators associated with the one of the one or more surgical procedures for the plurality of patients into at least one outcomes result (*See*, e.g., page 31, line 21 to page 32, line 5). The method still further comprises comparing a selected one of the at least one outcomes result to the norm (*See*, e.g., page 33, lines 1-10, and page 35, lines 22-23). The method additionally comprises generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (*See*, e.g., step 600 in Figure 2, page 32, lines 21-24).

The claimed invention, as set forth in claim 19, and as described and shown in the Specification and Figures 1 and 2 of the above-identified patent application, respectively, is directed to an apparatus for collecting and reporting outcomes data for benchmarking medical procedures (*See*, e.g., page 11, lines 9-18). The apparatus comprises a data collection portion including one or more user interfaces located at one or more user entities, wherein the data collection portion collects first outcomes data sets for one or more indicators associated with one or more medical procedures in a first period of time for a plurality of individuals and second outcomes data sets for the one or more indicators associated with the one or more medical procedures in a second period of time for the plurality

of individuals (*See*, e.g., User Interfaces 500-560 in Figure 1, page 15, lines 7-11, page 18, lines 8-14, and page 20, lines 5-22). The apparatus also comprises a data processor portion to receive the first and second outcomes data sets for the one or more indicators associated with one of the one or more medical procedures from the data collection portion (*See*, e.g., Server 200 in Figure 1, page 15, line 18 to page 16, line 19). The data processor portion may comprise a converter portion to convert at least some of the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result (*See*, e.g., page 31, line 21 to page 32, line 5). The data processor portion may also comprise a norm establishing portion to establish a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals (*See*, e.g., step 500 in Figure 2, page 31, line 18 to page 32, line 5). The data processor portion may further comprise a comparison portion to compare a selected one of the at least one outcomes result to the norm (*See*, e.g., page 33, lines 1-10, and page 35, lines 22-23). The data processor portion may still

further comprise a report generation portion to generate at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (*See*, e.g., step 600 in Figure 2, page 32, lines 21-24).

The claimed invention, as set forth in claim 24, and as described and shown in the Specification and Figures 1 and 2 of the above-identified patent application, respectively, is directed to an article of manufacture for collecting and reporting outcomes data for benchmarking medical procedures (*See*, e.g., page 11, lines 9-18). The article of manufacture comprises at least one processor readable medium and instructions carried on the at least one processor readable medium, wherein the instructions are configured to be readable from the at least one processor readable medium by at least one processor and thereby cause the at least one processor to operate so as to collect and report outcomes data for benchmarking medical procedures (*See*, e.g., page 12, line 22 to page 13, line 15). Specifically, the at least one processor may operate so as to collect first outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities (*See*, e.g., step 200 in Figure 2, page 18, lines 8-14). The at

least one processor may also operate so as to establish a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals (*See*, e.g., step 500 in Figure 2, page 31, line 18 to page 32, line 5). The at least one processor may further operate so as to collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities (*See*, e.g., step 200 in Figure 2, page 20, lines 5-22). The at least one processor may still further operate so as to convert at least some of the second outcomes data for the one or more indicators sets associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result (*See*, e.g., page 31, line 21 to page 32, line 5). The at least one processor may still further operate so as to compare a selected one of the at least one outcomes result to the norm (*See*, e.g., page 33, lines 1-10, and page 35, lines 22-23). The at least one processor may additionally operate so as to generate at least one outcomes monitoring report comprising the selected one

of the at least one outcomes result and the norm (*See*, e.g., step 600 in Figure 2, page 32, lines 21-24).

The claimed invention, as set forth in claim 25, and as described and shown in the Specification and Figures 1 and 2 of the above-identified patent application, respectively, is directed to at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to collect and report outcomes data for benchmarking medical procedures (*See*, e.g., page 11, lines 9-18; page 12, line 22 to page 13, line 15). Specifically, the at least one processor may be instructed to collect first outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities (*See*, e.g., step 200 in Figure 2, page 18, lines 8-14). The at least one processor may also be instructed to establish a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals (*See*, e.g., step 500 in Figure 2, page 31, line 18 to page 32, line 5). The at least one processor may further be

instructed to collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities (*See*, e.g., step 200 in Figure 2, page 20, lines 5-22). The at least one processor may still further be instructed to convert at least some of the second outcomes data for the one or more indicators sets associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result (*See*, e.g., page 31, line 21 to page 32, line 5). The at least one processor may still further be instructed to compare a selected one of the at least one outcomes result to the norm (*See*, e.g., page 33, lines 1-10, and page 35, lines 22-23). The at least one processor may additionally be instructed to generate at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (*See*, e.g., step 600 in Figure 2, page 32, lines 21-24).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-21 and 23-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts ("Gatts") in view of U.S. Patent No. 6,650,932 to Menzie

et al. ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin").

ARGUMENT

The Appellants respectfully appeal the decision of the Examiner to finally reject claims 1-21 and 23-30 of the above-identified patent application.

I. THE OBVIOUSNESS REJECTION OF CLAIMS 1-21 AND 23-30

The Examiner asserts that claims 1-21 and 23-30 should be rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts ("Gatts") in view of U.S. Patent No. 6,650,932 to Menzie *et al.* ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin"). This rejection is respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary

considerations," of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An "expansive and flexible approach" should be applied when determining obviousness based on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some "reason that would have prompted" a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. KSR, 127 S. Ct. at 1740-41.

A. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 1

Regarding claim 1, the Examiner asserts that Menzie discloses "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. However, Menzie issued November 18, 2003, from U.S.

Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Appellants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

Specifically, Appellants respectfully submit that the declarations submitted on November 9, 2005, provide a showing of conception prior to the Menzie reference date, as well as due diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Also, upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application

claims priority to U.S. Provisional Patent Application No. 60/252,129.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Appellants have done) in a declaration, but actual dates of diligence must be provided (which Appellants have provided) (see MPEP 715.07).

In view of the foregoing, Appellants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

At least in view of the foregoing, Appellants respectfully request that the aforementioned obviousness rejection of independent claim 1 be withdrawn.

Also regarding claim 1, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Appellants respectfully disagree.

Regarding Gatts, Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in

the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data sets "associated with one or more medical procedures for a plurality of individuals," as set forth in independent claim 1. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "a medical procedure," as recited in independent claim 1. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with the monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "a medical procedure."

Appellants also respectfully submit that Gatts fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising "establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the

first outcomes data sets," as recited in independent claims 1. The Examiner relies on the abstract of Gatts to disclose "establishing a norm based at least in part on an outcomes data group," as claimed. However, Appellants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and fails to disclose, or even suggest, "establishing a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Appellants agree, that Gatts fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed in independent claim 1. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Appellants respectfully disagree. Specifically,

Appellants respectfully submit that even assuming arguendo that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of independent claim 1. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, e.g., Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as alleged by the Examiner, Appellants further respectfully submit that it would not have

been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Appellants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See*, Gatts, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, Gatts, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. *See*, Menzie, column 4, lines 1-3. Therefore, Appellants

respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Appellants additionally respectfully submit that Gatts and Menzie, take either alone or in combination, fail to disclose, or even suggest, a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) in any manner. In contrast, the present application claims a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a surgical

center) against multiple other medical facilities (e.g., surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

Lastly, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie because Menzie's teaching of collecting second outcomes data sets from a plurality of individuals would improve Gatts' system by efficiently collecting medical data from geographically dispersed devices and processing such data in an efficient manner according to the teachings of Lin. Appellants respectfully disagree. In particular, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and Menzie relate to health testing and evaluation of treatments for an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control

samples from a common lot of control materials. *See*, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. *See*, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by Gatts and Menzie based upon the collection of medical data from laboratory instruments as taught by Lin.

At this point, Appellants would like to emphasize to the Board that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine

references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, Appellants respectfully submit that independent claim 1 is allowable over Gatts, Menzie, and Lin, taken either alone or in combination.

B. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIMS 2-10 AND 26

Regarding claims 2-10 and 26, these claims are dependent upon independent claim 1. Thus, since independent claim 1 should be allowable as discussed above, claims 2-10 and 26 should also be allowable at least by virtue of their dependency on independent claim 1. Moreover, these claims recite additional features which are not disclosed, or even suggested, by Gatts, Menzie, and Lin. Thus, these claims are separately patentable over Gatts in view of Menzie and further in view of Lin for at least the reasons stated below.

1. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 2

Claim 2 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose transmitting the first and second outcomes data sets for the one or more

indicators associated with the one of the one or more medical procedures for the plurality of individuals to a data processor, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 2.

2. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 3

Claim 3 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose selectively restricting access to the at least one outcomes monitoring report, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 3.

3. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 4

Claim 4 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose posting the at least one outcomes monitoring report to a webpage, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition,

Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 4.

4. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 5

Claim 5 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose selectively restricting access to the webpage, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 5.

5. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 6

Claim 6 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose collecting the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals from at least one user entity at a plurality of discrete intervals, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view

of Menzie and further in view of Lin fails to show each and every limitation of claim 6.

6. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 7

Claim 7 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose generating the at least one outcomes monitoring report from at least two of the plurality of discrete intervals, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 7.

7. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 8

Claim 8 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose collecting the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at the one or more user entities; and individually identifying and converting the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the

plurality of individuals located at each user entity of the one or more user entities; wherein the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at the one or more user entities comprises the outcomes data group, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 8.

8. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 9

Claim 9 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the at least one outcomes monitoring report includes the at least one outcomes result for a selected user entity of the one or more user entities and at least one comparison of the norm to the least one outcomes result for the selected user entity, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 9.

9. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 10

Claim 10 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 10.

10. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 26

Claim 26 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 1. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 26.

C. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 11

Regarding claim 11, the Examiner asserts that Menzie discloses "collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients," as claimed. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Appellants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

Specifically, Appellants respectfully submit that the declarations submitted on November 9, 2005, provide a showing of

conception prior to the Menzie reference date, as well as due diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Also, upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application claims priority to U.S. Provisional Patent Application No. 60/252,129.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Appellants have done) in a declaration, but actual dates of diligence must be provided (which Appellants have provided) (see MPEP 715.07).

In view of the foregoing, Appellants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

At least in view of the foregoing, Appellants respectfully request that the aforementioned obviousness rejection of independent claim 11 be withdrawn.

Also regarding independent claim 11, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Appellants respectfully disagree.

Regarding Gatts, Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data sets "associated with one or more surgical procedures for a plurality of patients," as set forth in independent claim 11. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "one or more surgical procedures," as recited in independent claim 11. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with the monitored data and

to provide an optimized level of reconditioning therapy, and fails to disclose "one or more surgical procedures."

Appellants also respectfully submit that Gatts fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising "establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first primary source surgical procedures outcomes data sets," as recited in independent claims 11. The Examiner relies on the abstract of Gatts to disclose "establishing a norm based at least in part on an outcomes data group," as claimed. However, Appellants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, Gatts, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and fails to disclose, or even suggest, "establishing a norm based at least in part on an outcomes data group, the

outcomes data group comprising a plurality of the first primary source surgical procedures outcomes data sets," as claimed.

Furthermore, the Examiner asserts, and Appellants agree, that Gatts fails to disclose, or even suggest, "collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one of the one or more surgical procedures for the plurality of patients," as claimed in independent claim 11. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Appellants respectfully disagree. Specifically, Appellants respectfully submit that even assuming arguendo that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of independent claim 11. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, e.g., Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's

physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, "collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients," as claimed.

Assuming arguendo that Menzie does disclose "collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients," as alleged by the Examiner, Appellants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Appellants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See,*

Gatts, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, Gatts, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. *See*, Menzie, column 4, lines 1-3. Therefore, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Appellants additionally respectfully submit that Gatts and Menzie, take either alone or in combination, fail to disclose, or even suggest, a medical benchmarking procedures using one or more user interfaces located at one or more surgical centers

(e.g., user entities and surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, a medical benchmarking procedures using one or more user interfaces located at one or more surgical centers (e.g., user entities and surgical centers) in any manner. In contrast, the present application claims a medical benchmarking procedure using one or more user interfaces located at one or more surgical centers (e.g., user entities and surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., user entities and surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a user entity or surgical center) against multiple other medical facilities (e.g., user entities and surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

Lastly, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie because Menzie's teaching of collecting second outcomes data sets from a plurality of individuals would improve Gatts' system by efficiently collecting medical data from geographically dispersed devices and processing such data in an efficient manner according to the teachings of Lin. Appellants respectfully disagree. In particular, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and Menzie relate to health testing and evaluation of treatments for an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control samples from a common lot of control materials. *See*, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data

from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. *See*, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by Gatts and Menzie based upon the collection of medical data from laboratory instruments as taught by Lin.

At this point, Appellants would like to emphasize to the Board that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, Appellants respectfully submit that independent claim 11 is allowable over Gatts, Menzie, and Lin, taken either alone or in combination.

D. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIMS 12-18 AND 27

Regarding claims 12-18 and 27, these claims are dependent upon independent claim 11. Thus, since independent claim 11 should be allowable as discussed above, claims 12-18 should also be allowable at least by virtue of their dependency on independent claim 11. Moreover, these claims recite additional features which are not disclosed, or even suggested, by Gatts, Menzie, and Lin. Thus, these claims are separately patentable over Gatts in view of Menzie and further in view of Lin for at least the reasons stated below.

1. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 12

Claim 12 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose transmitting the first and second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients to a data processor, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 12.

2. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 13

Claim 13 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose selectively restricting access to the at least one outcomes monitoring report, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 13.

3. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 14

Claim 14 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose posting the at least one outcomes monitoring report to a webpage, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 14.

4. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 15

Claim 15 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose selectively

restricting access to the webpage, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 15.

5. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 16

Claim 16 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose individually identifying and converting the second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for each surgical center of the one or more surgical centers; wherein the second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for a plurality of patients from the one or more surgical centers comprises the outcomes data group, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 16.

6. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 17

Claim 17 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the at least one outcomes monitoring report includes the at least one outcomes result for a selected surgical center of the one or more surgical centers and at least one comparison of the norm to the selected one of the least one outcomes result for the selected surgical center, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 17.

7. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 18

Claim 18 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 11, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition,

Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 18.

8. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 27

Claim 27 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the set of indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 11. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 18.

E. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 19

Regarding claim 19, the Examiner asserts that Menzie discloses a data collection portion collects "second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures in a second period of time for the plurality of individuals," as claimed. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Appellants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

Specifically, Appellants respectfully submit that the declarations submitted on November 9, 2005, provide a showing of conception prior to the Menzie reference date, as well as due diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Also, upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application claims priority to U.S. Provisional Patent Application No. 60/252,129.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Appellants have done) in a declaration, but actual dates of diligence must be provided (which Appellants have provided) (see MPEP 715.07).

In view of the foregoing, Appellants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

At least in view of the foregoing, Appellants respectfully request that the aforementioned obviousness rejection of independent claim 19 be withdrawn.

Also regarding claim 19, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Appellants respectfully disagree.

Regarding Gatts, Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data

sets "associated with one or more medical procedures," in a first period of time and in a second period of time "for a plurality of individuals," as set forth in independent claim 19. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "one or more medical procedures," as recited in independent claim 19. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with the monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "one or more medical procedures."

Appellants also respectfully submit that Gatts fails to disclose, or even suggest, an apparatus for collecting and reporting outcomes data for benchmarking medical procedures comprising "a nom establishing portion to establish a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets,"

as recited in independent claims 19. The Examiner relies on the abstract of Gatts to disclose "a norm establishing portion to establish a norm based at least in part on an outcomes data group," as claimed. However, Appellants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and fails to disclose, or even suggest, "a norm establishing portion to establish a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Appellants agree, that Gatts fails to disclose, or even suggest, "a data collection portion including one or more user interfaces located at one or more user entities," wherein the data collection portion collects "second outcomes data sets for the one or more indicators associated with the one or more medical procedures in a second period of time for the plurality of individuals," as claimed in independent claim 19. The Examiner relies on column

2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Appellants respectfully disagree. Specifically, Appellants respectfully submit that even assuming arguendo that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of independent claim 19. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, that the data collection portion collects "second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures in a second period of time for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose that the data collection portion collects "second outcomes data sets for the

one or more indicators associated with the one of the one or more medical procedures in a second period of time for the plurality of individuals," as alleged by the Examiner, Appellants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Appellants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See*, Gatts, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, Gatts, column 3, lines 39-47.

Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. *See*, Menzie, column 4, lines 1-3. Therefore, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Appellants additionally respectfully submit that Gatts and Menzie, take either alone or in combination, fail to disclose, or even suggest, a medical benchmarking apparatus using one or more user interfaces located at one or more user entities (e.g., surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, a medical benchmarking apparatus using one or more user interfaces located at one or more user entities (e.g., surgical centers) in any manner. In contrast, the present application claims a medical benchmarking apparatus using one or more user interfaces located at one or more user entities (e.g., surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility

(e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a surgical center) against multiple other medical facilities (e.g., surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

Lastly, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie because Menzie's teaching of collecting second outcomes data sets from a plurality of individuals would improve Gatts' system by efficiently collecting medical data from geographically dispersed devices and processing such data in an efficient manner according to the teachings of Lin. Appellants respectfully disagree. In particular, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and Menzie relate to health testing and evaluation of treatments for

an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control samples from a common lot of control materials. *See*, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. *See*, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by Gatts and Menzie based upon the collection of medical data from laboratory instruments as taught by Lin.

At this point, Appellants would like to emphasize to the Board that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including

portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, Appellants respectfully submit that independent claim 19 is allowable over Gatts, Menzie, and Lin, taken either alone or in combination.

F. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIMS 20, 21, 23, AND 28

Regarding claims 20, 21, 23, and 28 these claims are dependent upon independent claim 19. Thus, since independent claim 19 should be allowable as discussed above, claims 20, 21, 23, and 28 should also be allowable at least by virtue of their dependency on independent claim 19. Moreover, these claims recite additional features which are not disclosed, or even suggested, by Gatts, Menzie, and Lin. Thus, these claims are separately patentable over Gatts in view of Menzie and further in view of Lin for at least the reasons stated below.

1. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 20

Claim 20 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose a webpage portion to post the at least one outcomes monitoring report to a webpage, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 19. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 20.

2. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 21

Claim 21 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose a security portion to selectively restrict access to the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals, the at least one outcomes result and the at least one outcomes monitoring report, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 19. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 21.

3. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 23

Claim 23 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals are primary source data sets, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 19. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 23.

4. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 28

Claim 28 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 19. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 28.

G. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 24

Regarding claim 24, the Examiner asserts that Menzie discloses that "collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Appellants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

Specifically, Appellants respectfully submit that the declarations submitted on November 9, 2005, provide a showing of conception prior to the Menzie reference date, as well as due

diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Also, upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application claims priority to U.S. Provisional Patent Application No. 60/252,129.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Appellants have done) in a declaration, but actual dates of diligence must be provided (which Appellants have provided) (see MPEP 715.07).

In view of the foregoing, Appellants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

At least in view of the foregoing, Appellants respectfully request that the aforementioned obviousness rejection of independent claim 24 be withdrawn.

Also regarding claim 24, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Appellants respectfully disagree.

Regarding Gatts, Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data sets "associated with one or more medical procedures for a plurality of individuals," as set forth in independent claim 24. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "one or more medical procedures," as recited in independent claim 24. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with the monitored data and

to provide an optimized level of reconditioning therapy, and fails to disclose "one or more medical procedures."

Appellants also respectfully submit that Gatts fails to disclose, or even suggest, an article of manufacture for collecting and reporting outcomes data for benchmarking medical procedures comprising to "establish a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets," as recited in independent claims 24. The Examiner relies on the abstract of Gatts to disclose to "establish a norm based at least in part on an outcomes data group," as claimed. However, Appellants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, Gatts, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and fails to disclose, or even suggest, to "establish a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Appellants agree, that Gatts fails to disclose, or even suggest, to "collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed in independent claim 24. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Appellants respectfully disagree. Specifically, Appellants respectfully submit that even assuming arguendo that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of independent claim 24. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, to "collect second outcomes data sets

for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose to "collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as alleged by the Examiner, Appellants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Appellants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See*, Gatts, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended

reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, Gatts, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. *See*, Menzie, column 4, lines 1-3. Therefore, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Appellants additionally respectfully submit that Gatts and Menzie, take either alone or in combination, fail to disclose, or even suggest, an article of manufacture for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, an article of manufacture for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) in any

manner. In contrast, the present application claims an article of manufacture for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a surgical center) against multiple other medical facilities (e.g., surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

Lastly, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie because Menzie's teaching of collecting second outcomes data sets from a plurality of individuals would improve Gatts' system by efficiently collecting medical data from geographically

dispersed devices and processing such data in an efficient manner according to the teachings of Lin. Appellants respectfully disagree. In particular, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and Menzie relate to health testing and evaluation of treatments for an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control samples from a common lot of control materials. *See*, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. *See*, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by

Gatts and Menzie based upon the collection of medical data from laboratory instruments as taught by Lin.

At this point, Appellants would like to emphasize to the Board that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, Appellants respectfully submit that independent claim 24 is allowable over Gatts, Menzie, and Lin, taken either alone or in combination.

H. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 29

Regarding claim 29, this claim is dependent upon independent claim 24. Thus, since independent claim 24 should be allowable as discussed above, claim 29 should also be allowable at least by virtue of their dependency on independent claim 24. Moreover, this claim recites additional features which are not disclosed, or even suggested, by Gatts, Menzie,

and Lin. Thus, these claims are separately patentable over Gatts in view of Menzie and further in view of Lin for at least the reasons stated below.

1. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 29

Claim 29 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 24. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 29.

I. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 25

Regarding claim 25, the Examiner asserts that Menzie discloses "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Appellants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

Specifically, Appellants respectfully submit that the declarations submitted on November 9, 2005, provide a showing of conception prior to the Menzie reference date, as well as due diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Also, upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application claims priority to U.S. Provisional Patent Application No. 60/252,129.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Appellants have done) in a declaration, but actual dates of diligence must be provided (which Appellants have provided) (see MPEP 715.07).

In view of the foregoing, Appellants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

At least in view of the foregoing, Appellants respectfully request that the aforementioned obviousness rejection of independent claim 25 be withdrawn.

Also regarding claim 25, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Appellants respectfully disagree.

Regarding Gatts, Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data

sets "associated with one or more medical procedures for a plurality of individuals," as set forth in independent claim 25. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "one or more medical procedures," as recited in independent claim 25. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with the monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "one or more medical procedures."

Appellants also respectfully submit that Gatts fails to disclose, or even suggest, at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to collect and report outcomes data for benchmarking medical procedures comprising the steps of "establishing a norm based at least in part on an outcomes data

group, the outcomes data group comprising a plurality of the first outcomes data sets," as recited in independent claims 25. The Examiner relies on the abstract of Gatts to disclose "establishing a norm based at least in part on an outcomes data group," as claimed. However, Appellants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and fails to disclose, or even suggest, "establishing a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Appellants agree, that Gatts fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed in independent claim 25. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed

limitation. Appellants respectfully disagree. Specifically, Appellants respectfully submit that even assuming arguendo that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of independent claim 25. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, e.g., Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as alleged by the Examiner,

Appellants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Appellants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See*, Gatts, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, Gatts, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner.

See, Menzie, column 4, lines 1-3. Therefore, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Appellants additionally respectfully submit that Gatts and Menzie, take either alone or in combination, fail to disclose, or even suggest, at least one processor readable medium storing a computer program of instructions for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, at least one processor readable medium for storing a computer program of instructions for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) in any manner. In contrast, the present application claims at least one processor readable medium for storing a computer program of instructions for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) wherein an outcomes monitoring report is generated

comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a surgical center) against multiple other medical facilities (e.g., surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

Lastly, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie because Menzie's teaching of collecting second outcomes data sets from a plurality of individuals would improve Gatts' system by efficiently collecting medical data from geographically dispersed devices and processing such data in an efficient manner according to the teachings of Lin. Appellants respectfully disagree. In particular, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and

Menzie relate to health testing and evaluation of treatments for an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control samples from a common lot of control materials. *See*, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. *See*, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by Gatts and Menzie based upon the collection of medical data from laboratory instruments as taught by Lin.

At this point, Appellants would like to emphasize to the Board that, as stated in MPEP § 2141.02, a prior art reference

must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, Appellants respectfully submit that independent claim 25 is allowable over Gatts, Menzie, and Lin, taken either alone or in combination.

J. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 30

Regarding claim 30, this claim is dependent upon independent claim 25. Thus, since independent claim 25 should be allowable as discussed above, claim 30 should also be allowable at least by virtue of their dependency on independent claim 25. Moreover, this claim recites additional features which are not disclosed, or even suggested, by Gatts, Menzie, and Lin. Thus, these claims are separately patentable over Gatts in view of Menzie and further in view of Lin for at least the reasons stated below.

1. THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS AGAINST CLAIM 30

Claim 30 is separately patentable because Gatts in view of Menzie and further in view of Lin fails to disclose that the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer, as claimed. The rejection of this claim is thus improper for the reasons set forth above with respect to claim 25. In addition, Gatts in view of Menzie and further in view of Lin fails to show each and every limitation of claim 30.

CONCLUSION

In view of the foregoing, Appellants respectfully submit that the Examiner has failed to establish a prima facie case of anticipation or obviousness against the rejected claims. Thus, Appellants respectfully submit that the final rejection of claims 1-21 and 23-30 is improper and the reversal of same is clearly in order and respectfully requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-0206, and please credit any excess fees to such deposit account.

Respectfully submitted,

Hunton & Williams LLP

By: _____
Thomas E. Anderson
Registration No. 37,063

TEA/DD

Hunton & Williams LLP
1900 K Street, N.W.
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201

Date: April 24, 2009

CLAIMS APPENDIX

1 (Previously Presented). A method for collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of:

collecting first outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities;

establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals;

collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities;

converting at least some of the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result;

comparing a selected one of the at least one outcomes

result to the norm; and

generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm.

2 (Previously Presented). The method of claim 1, further comprising the step of:

transmitting the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals to a data processor.

3 (Previously Presented). The method of claim 1, further comprising the step of:

selectively restricting access to the at least one outcomes monitoring report.

4 (Previously Presented). The method of claim 1, further comprising the step of:

posting the at least one outcomes monitoring report to a webpage.

5 (Previously Presented). The method of claim 4, further

comprising the step of:

selectively restricting access to the webpage.

6 (Previously Presented). The method of claim 1, further comprising the step of:

collecting the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals from at least one user entity at a plurality of discrete intervals.

7 (Previously Presented). The method of claim 6, further comprising the step of:

generating the at least one outcomes monitoring report from at least two of the plurality of discrete intervals.

8 (Previously Presented). The method of claim 1, further comprising the steps of:

collecting the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at the one or more user entities; and

individually identifying and converting the second outcomes data sets for the one or more indicators associated with the one

of the one or more medical procedures for the plurality of individuals located at each user entity of the one or more user entities;

wherein the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at the one or more user entities comprises the outcomes data group.

9 (Previously Presented). The method of claim 8, wherein the at least one outcomes monitoring report includes the at least one outcomes result for a selected user entity of the one or more user entities and at least one comparison of the norm to the least one outcomes result for the selected user entity.

10 (Previously Presented). At least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1.

11 (Previously Presented). A method for collecting and reporting outcomes data for benchmarking surgical procedures comprising the steps of:

collecting first primary source surgical procedures outcomes data sets including a plurality of responses to a set of indicators associated with one or more surgical procedures for a plurality of patients in a first period of time via one or more user interfaces located at one or more surgical centers;

establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with one or more surgical procedures for the plurality of patients;

collecting second primary source surgical procedures outcomes data sets including a plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients in a second period of time via the one or more user interfaces located at the one or more surgical centers;

converting at least some of the second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one of the one or more surgical procedures for the plurality of patients into at least one outcomes result;

comparing a selected one of the at least one outcomes

result to the norm; and

generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm.

12 (Previously Presented). The method of claim 11, further comprising the step of:

transmitting the first and second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for the plurality of patients to a data processor.

13 (Previously Presented). The method of claim 11, further comprising the step of:

selectively restricting access to the at least one outcomes monitoring report.

14 (Previously Presented). The method of claim 11, further comprising the step of:

posting the at least one outcomes monitoring report to a webpage.

15 (Previously Presented). The method of claim 14, further comprising the step of:

selectively restricting access to the webpage.

16 (Previously Presented). The method of claim 11, further comprising the steps of:

individually identifying and converting the second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for each surgical center of the one or more surgical centers;

wherein the second primary source surgical procedures outcomes data sets including the plurality of responses to the set of indicators associated with the one or more surgical procedures for a plurality of patients from the one or more surgical centers comprises the outcomes data group.

17 (Previously Presented). The method of claim 16, wherein the at least one outcomes monitoring report includes the at least one outcomes result for a selected surgical center of the one or more surgical centers and at least one comparison of the norm to the selected one of the least one outcomes result for the selected surgical center.

18 (Previously Presented). At least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 11.

19 (Previously Presented). An apparatus for collecting and reporting outcomes data for benchmarking medical procedures, the apparatus comprising:

a data collection portion including one or more user interfaces located at one or more user entities, wherein the data collection portion collects first outcomes data sets for one or more indicators associated with one or more medical procedures in a first period of time for a plurality of individuals and second outcomes data sets for the one or more indicators associated with the one or more medical procedures in a second period of time for the plurality of individuals;

a data processor portion to receive the first and second outcomes data sets for the one or more indicators associated with one of the one or more medical procedures from the data collection portion, wherein the data processor portion comprises:

a converter portion to convert at least some of the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result;

a norm establishing portion to establish a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals;

a comparison portion to compare a selected one of the at least one outcomes result to the norm; and

a report generation portion to generate at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm.

20 (Previously Presented). The apparatus of claim 19, further comprising a webpage portion to post the at least one outcomes monitoring report to a webpage.

21 (Previously Presented). The apparatus of claim 19, further comprising a security portion to selectively restrict access to the first and second outcomes data sets for the one or more

indicators associated with the one of the one or more medical procedures for the plurality of individuals, the at least one outcomes result and the at least one outcomes monitoring report.

22 (Cancelled).

23 (Previously Presented). The apparatus of claim 19, wherein the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals are primary source data sets.

24 (Previously Presented). An article of manufacture for collecting and reporting outcomes data for benchmarking medical procedures, the article of manufacture comprising:

at least one processor readable medium; and

instructions carried on the at least one processor readable medium;

wherein the instructions are configured to be readable from the at least one processor readable medium by at least one processor and thereby cause the at least one processor to operate so as to:

collect first outcomes data sets for one or more

indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities;

establish a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals;

collect second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities;

convert at least some of the second outcomes data for the one or more indicators sets associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result;

compare a selected one of the at least one outcomes result to the norm; and

generate at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm.

25 (Previously Presented). At least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to collect and report outcomes data for benchmarking medical procedures by performing the steps of:

collecting first outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in a first period of time via one or more user interfaces located at one or more user entities;

establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals;

collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals in a second period of time via the one or more user interfaces located at the one or more user entities;

converting at least some of the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result;

comparing a selected one of the at least one outcomes result to the norm; and

generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm.

26. (Previously Presented). The method of claim 1, wherein the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer.

27. (Previously Presented). The method of claim 11, wherein the set of indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer.

28. (Previously Presented). The method of claim 19, wherein the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer.

29. (Previously Presented). The method of claim 24, wherein the one or more indicators including at least one of verbal

responses, measured analytical data, and observations of a third-party observer.

30. (Previously Presented). The method of claim 25, wherein the one or more indicators including at least one of verbal responses, measured analytical data, and observations of a third-party observer.

EVIDENCE APPENDIX

[NONE]

RELATED PLEADINGS APPENDIX

[NONE]